Complete Summary

GUIDELINE TITLE

Device selection and outcomes of aerosol therapy: evidence-based guidelines: American College of Chest Physicians/American College of Asthma, Allergy, and Immunology.

BIBLIOGRAPHIC SOURCE(S)

Dolovich MB, Ahrens RC, Hess DR, Anderson P, Dhand R, Rau JL, Smaldone GC, Guyatt G. Device selection and outcomes of aerosol therapy: evidence-based guidelines: American College of Chest Physicians/American College of Asthma, Allergy, and Immunology. Chest 2005 Jan;127(1):335-71. [142 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
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SCOPE

DISEASE/CONDITION(S)

- Asthma
- Chronic obstructive pulmonary disease (COPD)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Emergency Medicine
Family Practice
Internal Medicine
Nursing
Pediatrics
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians
Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

- To compare the efficacy and adverse effects of treatment using nebulizers versus pressurized metered-dose inhalers (MDIs) with or without a spacer/holding chamber versus dry powder inhalers (DPIs) as delivery systems for $beta_2$-agonists, anticholinergic agents, and corticosteroids for several commonly encountered clinical settings and patient populations
- To provide recommendations to clinicians to aid them in selecting a particular aerosol delivery device for their patients

TARGET POPULATION

Patients of all ages with asthma and chronic obstructive pulmonary disease (COPD) in varied clinical settings (outpatient, emergency department, hospitalized inpatient, or intensive care settings)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Small-volume jet nebulizers (compressed air nebulizers)
2. Ultrasonic nebulizers
3. Metered-dose inhalers (MDIs)
4. Breath actuated MDIs
5. Spacer devices intended for use with MDIs:
    - Holding chambers (one way valve)
    - Reverse-flow spacers (blind reservoir)
    - Other
6. Dry powder inhalers (DPIs)

MAJOR OUTCOMES CONSIDERED

The guideline developers tabulated a total of 254 outcomes, from which they created a taxonomy of 10 categories:

- Forced expiratory volume in one second (FEV_1)
- Peak flow
- Mechanics (specific airway conductance [sGaw])
- Symptoms/physical findings (asthma score, dyspnea score, wheeze, sleep disturbances, and dyspnea on exertion)
- Forced vital capacity (FVC)
- Forced expiratory flow, midexpiratory phase ($FEF_{25-75\%}$)
- Blood gas (SaO_2, PO_2, PCO_2, pH)
- Adrenergic use ($beta_2$-adrenergic use, total number of doses, bronchodilator puffs)
- Technique/preference
- Heart rate, blood pressure, electrocardiogram

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The databases that were searched were MEDLINE, Embase, and the Cochrane Library. A broad search strategy was chosen to combine terms relating to aerosol devices or drugs with those relating to the diseases of interest in various patient groups and in a number of clinical settings. Only randomized controlled trials (RCTs) in human subjects published in English were selected. The search identified an initial set of approximately 2,100 publications spanning the years 1972 to 2000. Two reviewers independently assessed each abstract of these publications to determine whether they met the eligibility criteria. This review identified 394 RCTs assessing inhaled corticosteroid, beta2-agonist, and anticholinergic agents that were delivered by metered dose inhaler (MDI), MDI with spacer/holding chamber, nebulizer, or dry powder inhaler (DPI). These 394 studies were coded (for setting, population, disease, and device) to provide a second screening to identify studies in which the same drug was administered with different devices. Studies were excluded if they only compared devices of the same type (e.g., DPI with DPI) or only compared oral or parenteral therapy with the aerosol therapy.

NUMBER OF SOURCE DOCUMENTS

Publications identified: 2,100

Publications meeting eligibility criteria: 394

Publications in which data was extracted: 131

Publications containing useable data: 59

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of the Evidence

Good = Evidence is based on good randomized controlled trials or meta-analyses.

Fair = Evidence is based on other controlled trials or randomized controlled trials with minor flaws.

Low = Evidence based on nonrandomized, case-control, or other observational studies.

Expert opinion = Evidence is based on the consensus of the carefully selected panel of experts in the topic field. There are no studies that meet the criteria for inclusion in the literature review.

The levels of net benefit to the patient (adjusted for risk) are based on clinical assessment of the test or procedure: substantial, intermediate, small/weak, none, conflicting, negative.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data were extracted from the remaining 131 studies. A total of 254 outcomes were tabulated (see Table 4, available on-line only). Because this proved unwieldy, the guideline developers created a taxonomy of 10 categories (see Table 5 in the original guideline document) and, as many of the outcomes were similar expressions of the same measurement, specified a hierarchy of outcomes within this taxonomy. Of the 131 studies, only 59 proved to have useable data (see Table 6 in the original guideline document). These studies primarily tested $beta_2$-agonists. Few studies of corticosteroids met the guideline developer's eligibility criteria.

Separate meta-analyses were carried out for each specific clinical setting being considered. The weighted standardized difference between treatment groups in the outcome of interest was calculated using the mean scores and their standard deviations (SDs). The guideline developers combined results across end points of forced expiratory volume in one second (FEV_1), peak flow, and specific airway conductance (sGaw), and calculated the effect size in standard deviation (SD) units. For studies that made measurements at multiple time points, the last time point was used for analysis. For studies with multiple doses, analyses using the first dose and the last dose were performed. All outcomes reported are in SD units. In studies that provided data for more than one of these outcomes, the

developers used the outcome that was highest in the hierarchy. To assess whether the magnitude of the heterogeneity of differences in the apparent treatment effect across studies was greater than one might expect by chance, the developers conducted a test based on the chi-square distribution with N - 1 degree of freedom, where N is the number of studies. No important effects were seen in any of the group analyses, and there was very little heterogeneity in any of the data.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The intent of this project was to assess the available scientific evidence addressing the question of whether device selection affects efficacy and the adverse effects of treatment. Therefore, the guideline developers set out to systematically review relevant evidence from randomized, placebo-controlled clinical trials and to provide general recommendations based on the tradeoffs that this evidence provides. The recommendations relate to issues that clinicians should consider in selecting a particular therapeutic aerosol delivery device for their patients in each of several commonly encountered clinical settings.

Members of the Writing Committee assumed responsibility for drafting individual sections of the final document, including the recommendations. To grade the strength of the recommendations, developers used a system adopted by the Health and Science Policy Committee of the American College of Chest Physicians. Grading of the strength of the recommendations was based on both the quality of the evidence and the net benefit of the device. The draft document was reviewed by all members of the Writing Committee for content and accuracy.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

Grading of the strength of the recommendations is based on both the quality of the evidence and the net benefit of the diagnostic or therapeutic procedure.

Quality of Evidence	Net Benefit					
	Substantial	Intermediate	Small / Weak	None	Conflicting	Negative
Good	A	A	B	D	I	D
Fair	A	B	C	D	I	D
Low	B	C	C	I	I	D
Expert opinion	E/A	E/B	E/C	I	I	E/D

A = Strong recommendation

B = Moderate recommendation

C = Weak recommendation

D = Negative recommendation

I = No recommendation possible (inconclusive)

E/A = Strong recommendation based on expert opinion only

E/B = Moderate recommendation based on expert opinion only

E/C = Weak recommendation based on expert opinion only

E/D = Negative recommendation based on expert opinion only

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse™ (NGC): The following recommendations summarize the content of the guideline. Please refer to the original guideline document for more information. The quality of the evidence (good, fair, low, expert opinion), the net benefit (substantial, intermediate, small/weak, none, conflicting, negative), and the strength of recommendations (A-D, I, E/A, E/B, E/C, E/D) are listed at the end of the "Major Recommendations" field.

When selecting an aerosol delivery device, the following questions should be considered:

1. In what devices is the desired drug available?
2. What device is the patient likely to be able to use properly, given the patient's age and the clinical setting?
3. For which device and drug combination is reimbursement available?
4. Which devices are the least costly?
5. Can all types of inhaled asthma/chronic obstructive pulmonary disease (COPD) drugs that are prescribed for the patient (e.g., short-acting beta-agonist, corticosteroid, anticholinergic, and long-acting beta-agonist) be

delivered with the same type of device (e.g., nebulizer, manually actuated metered dose inhaler [MDI], MDI with spacer/holding chamber, or breath-actuated device [i.e., automatically activated MDI or dry powder inhaler (DPI)])? Using the same type of device for all inhaled drugs may facilitate patient teaching and decrease the chance for confusion among devices that require different inhalation techniques.
6. Which devices are the most convenient for the patient, family (outpatient use), or medical staff (acute care setting) to use, given the time required for drug administration and device cleaning, and the portability of the device?
7. How durable is the device?
8. Does the patient or clinician have any specific device preferences?

Whichever device is chosen, it is clear that proper patient education on its use is critical and that the assessment of inhalation technique should be part of subsequent visits to the physician.

Aerosol Delivery of Short-Acting Beta$_2$-Agonists in the Hospital Emergency Department

1. Both the nebulizer and MDI with spacer/holding chamber are appropriate for the delivery of short-acting beta$_2$-agonists in the emergency department (ED). Quality of evidence: good; net benefit: substantial; strength of recommendation: A.
2. Because data for DPIs are limited, and high quality data for standard MDIs (without spacer/holding chamber) and breath-actuated MDIs are unavailable, the guideline developers are unable to recommend the use of these devices in the ED until more information is available. Quality of evidence: low; net benefit: none; strength of recommendation: I.
3. Many factors would lead the clinician to appropriately select a particular type of aerosol delivery device in this setting. These factors include the patient's ability to use the device correctly, the preferences of the patient for the device, the unavailability of an appropriate drug/device combination, the compatibility between the drug and delivery device, the lack of time or skills to properly instruct the patient in the use of the device or to monitor the appropriate use, and the cost of therapy. Quality of evidence: low; net benefit: substantial; strength of recommendation: B.

Aerosol Delivery of Short-Acting Beta$_2$-Agonists in the Inpatient Hospital Setting

1. Both nebulizers and MDIs with spacer/holding chambers are appropriate for use in the inpatient setting. Quality of evidence: good; net benefit: substantial; strength of recommendation: A.
2. Because the data for DPIs, standard MDIs without spacer/holding chambers, and breath-actuated MDIs have been inadequately studied in this setting, the guideline developers are unable to recommend the use of these devices in patients requiring hospitalization for asthma or COPD until more information is available. Quality of evidence: low; net benefit: none; strength of recommendation: I.
3. Many factors would lead the clinician to appropriately select a particular type of aerosol delivery device in this setting. These include the patient's inability to use the device correctly, the preferences of the patient for the device, the

unavailability of the drug/device combination, the compatibility between the drug and the delivery device, the lack of time or skills to properly instruct the patient in the use of the device or in monitoring the appropriate use, and the cost of therapy. Quality of evidence: low; net benefit: substantial; strength of recommendation: B.

Intermittent Versus Continuous Nebulizer Delivery of $Beta_2$-Agonists

1. Frequent intermittent nebulization and continuous nebulization are both appropriate alternatives in severely dyspneic patients in the ED or intensive care unit (ICU). Quality of evidence: good; net benefit: substantial; strength of recommendation: A.

Aerosolized $Beta_2$-Agonists in Patients Receiving Mechanical Ventilation

1. Both nebulizers and MDIs can be used to deliver beta-agonists to mechanically ventilated patients. Quality of evidence: fair; net benefit: substantial; strength of recommendation: A.
2. Careful attention to details of the technique employed for administering drugs by MDI or nebulizer to mechanically ventilated patients is critical, since multiple technical factors may have clinically important effects on the efficiency of aerosol delivery. Quality of evidence: low; net benefit: substantial; strength of recommendation: B.

Short-Acting Beta2-Agonists for Asthma in the Outpatient Setting

1. For treatment of asthma in the outpatient setting, both the MDI, used with or without spacer/holding chamber, and the DPI are appropriate for the delivery of short-acting $beta_2$-agonists. Quality of evidence: good; net benefit: substantial; strength of recommendation: A.
2. The appropriate selection of a particular type of aerosol delivery device in this setting includes the patient's ability to use the device correctly, the preferences of the patient for the device, the availability of the drug/device combination, the compatibility between the drug and delivery device, the lack of time or skills to properly instruct the patient in the use of the device or to monitor the appropriate use, the cost of the therapy, and the potential for reimbursement. Quality of evidence: low; net benefit: substantial; strength of recommendation: B.

Inhaled Corticosteroids for Asthma

1. For the treatment of asthma in the outpatient setting, both the MDI with a spacer/holding chamber and the DPI are appropriate devices for the delivery of inhaled corticosteroids. Quality of evidence: good; net benefit: substantial; strength of recommendation: A.
2. For outpatient asthma therapy, the selection of an appropriate aerosol delivery device for inhaled corticosteroids includes the patient's ability to use the device correctly, the preferences of the patient for the device, the availability of the drug/device combination, the compatibility between the drug and delivery device, the lack of time or skills to properly instruct the patient in the use of the device or monitor the appropriate use, the cost of

therapy, and the potential for reimbursement. Quality of evidence: low; net benefit: substantial; strength of recommendation: B.

Beta$_2$-Agonists and Anticholinergic Agents for COPD

1. For the treatment of COPD in the outpatient setting, the MDI, with or without spacer/holding chamber, the nebulizer, and the DPI are all appropriate for the delivery of inhaled beta$_2$-agonist and anticholinergic agents. Quality of evidence: good; net benefit: substantial; strength of recommendation: A.
2. For outpatient COPD therapy, the selection of an appropriate aerosol delivery device for inhaled beta$_2$-agonist and anticholinergic agents includes the patient's ability to use the device correctly, the preferences of the patient for the device, the availability of the drug/device combination, the compatibility between the drug and the delivery device, the lack of time or skills to properly instruct the patient in the use of the device or monitor its appropriate use, the cost of therapy, and the potential for reimbursement. Quality of evidence: low; net benefit: substantial; strength of recommendation: B.

Definitions:

Quality of the Evidence

Good = Evidence is based on good randomized controlled trials or meta-analyses.

Fair = Evidence is based on other controlled trials or randomized controlled trials with minor flaws.

Low = Evidence is based on nonrandomized, case-control, or other observational studies.

Expert Opinion = Evidence is based on the consensus of the carefully selected panel of experts in the topic field. There are no studies that meet the criteria for inclusion in the literature review.

Net Benefit

Substantial
Intermediate
Small/weak
None
Conflicting
Negative

Quality of Evidence	Net Benefit					
	Substantial	Intermediate	Small/Weak	None	Conflicting	Negative
Good	A	A	B	D	I	D
Fair	A	B	C	D	I	D
Low	B	C	C	I	I	D
Expert opinion	E/A	E/B	E/C	I	I	E/D

Strength of Recommendations

A = Strong recommendation

B = Moderate recommendation

C = Weak recommendation

D = Negative recommendation

I = No recommendation possible (inconclusive)

E/A = Strong recommendation based on expert opinion only

E/B = Moderate recommendation based on expert opinion only

E/C = Weak recommendation based on expert opinion only

E/D = Negative recommendation based on expert opinion only

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

- This guideline is intended to aid clinicians in selecting appropriate aerosol delivery devices for their patients.
- The use of inhaled aerosols allows selective treatment of the lungs directly by achieving high drug concentrations in the airway while reducing systemic adverse effects by minimizing systemic drug levels.

Benefits of Specific Devices

- Nebulizers: require minimal patient cooperation and coordination
- Metered dose inhalers (MDIs): quicker to use and highly portable
- Dry powder inhalers (DPIs): ease of use because they are breath actuated

POTENTIAL HARMS

Overall Potential Harms

A less than optimal technique can result in decreased drug delivery and potentially reduced efficacy. Improper inhaler technique is common among patients.

Potential Harms or Side Effects of Specific Devices

- Nebulizers: cumbersome and time consuming, increased heart rate, vomiting
- Metered dose inhalers (MDIs): require the most patient training to ensure coordination of proper use (up to 70% of patients fail to use them properly); oral candidiasis
- Dry powder inhalers (DPIs): require a relatively rapid rate of inhalation in order to provide the energy necessary for drug aerosolization (younger patients in acute distress may not be able to generate the necessary flow rate)

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The results of this systematic review were essentially the same in each of the clinical settings evaluate. None of the pooled meta-analyses showed a significant difference between devices in any efficacy outcome in any patient group. Thus, the relative effectiveness of delivery methods does not provide a clear basis for selecting one device over another. This does not mean that the device choice for a specific patient does not seem to matter. In essence, this says that each of the devices studied can work equally well in that setting in patients who can use them appropriately. This is an important statement because most studies, especially in the outpatient setting, select for patients who are capable of using each of the devices with the appropriate technique or train patients to use the appropriate technique. The randomized controlled trials (RCTs) included in this systematic review do not provide much information about who is likely to use one device or another properly, nor do they address many other considerations that are important for choosing a delivery device for a specific patient in a specific clinical situation. These include the ability to use the device, patient preference, the availability of equipment, and cost. While the clinician is still left to select the method of delivery based on these other considerations, the guideline developers have made general recommendations based on the results of the metaanalysis to guide the clinician in his/her selection of a delivery system. In addition, there are some obvious situations in which device selection clearly does matter. For example, in each of the clinical situations studied, there are some devices that were studied little or not at all. This appears to indicate a consensus that RCTs are not needed to determine that some devices are inappropriate for that clinical situation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Dolovich MB, Ahrens RC, Hess DR, Anderson P, Dhand R, Rau JL, Smaldone GC, Guyatt G. Device selection and outcomes of aerosol therapy: evidence-based guidelines: American College of Chest Physicians/American College of Asthma, Allergy, and Immunology. Chest 2005 Jan;127(1):335-71. [142 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Jan

GUIDELINE DEVELOPER(S)

American College of Allergy, Asthma and Immunology - Medical Specialty Society
American College of Chest Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Chest Physicians

GUIDELINE COMMITTEE

ACCP/ACAAI Evidence-based Guideline Panel on Device Selection and Outcomes of Aerosol Therapy

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Professor Dolovich has served as a speaker for Forest Laboratories, 3M Pharma, and Aventis, and as a consultant for GlaxoSmithKline and Delex Therapeutics, and has received research funding from 3M Pharma, Trudell Medical International, and Altana Pharma. Dr. Ahrens, in the past 12 months, has received research funding from or has had a consulting relationship with the following organizations with a potential financial interest in the subject of the manuscript: AstraZeneca; Aventis; Boehringer Ingelheim; GlaxoSmithKline; Innovata Biomed Limited; Medic-Aid Limited; Monaghan Medical Corporation; and 3M Corporation. Dr. Hess has served as a consultant for Pari and has received research funding from Cardinal Health. Dr. Anderson has participated in clinical trials for GlaxoSmithKline, Boehringer Ingelheim, Astra-Zeneca, and Novartis. Dr. Dhand has served as a speaker for GlaxoSmithKline and Boehringer Ingelheim, has sponsored meetings for GlaxoSmithKline, Boehringer Ingelheim, and Sepracor, and has performed research funded by Sepracor Inc and Omron. Dr. Rau has no financial interest or involvement in any organization with a direct financial interest in the subject of this article, but he has served as a consultant for Respironics, as a speaker for Sepracor Pharmaceutical, and as a consultant and speaker for and performed research funded by Trudell Medical International and Monaghan Medical Corporation. Dr. Smaldone has served as a consultant to several device and pharmaceutical companies that are connected to aerosol therapy, primarily the nebulization of drugs. Those companies with a direct financial interest in nebulization include Monaghan/Trudell Medical International, Aerogen, Pari, and Profile Therapeutics.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available to subscribers of Chest - The Cardiopulmonary and Critical Care Journal.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Device selection and outcomes of aerosol therapy: evidence-based guidelines American College of Chest Physicians/American College of Asthma, Allergy, and Immunology: executive summary. 2005 Jan. 14 p. Electronic copies: Available to subscribers of Chest - The Cardiopulmonary and Critical Care Journal.
- Inhaled medications and devices: tips and techniques [CD-ROM]. To order, please see the American College of Chest Physician's Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 11, 2005. The information was verified by the guideline developer on April 4, 2005.

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